

Application No. 10/731,741
Reply to final office action dated: September 11, 2006
Response dated: October 30, 2006

REMARKS / ARGUMENTS

By the present amendment, claims 1, 4, 17 and 22 have been amended as described below and claims 8, 14-16 and 24 have been cancelled. Claims 1, 2, 4, 10-13, 17 and 22 are pending in the application. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. The Applicants reserve the right to pursue any of the deleted subject matter in a further continuation, continuation-in-part or divisional application. The amendment does not contain new matter and its entry is respectfully requested.

The final official action dated September 11, 2006 has been carefully considered. It is believed that the amended claims submitted herewith and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

35 USC § 112, first paragraph

The Examiner has rejected claims 1, 2, 4, 8, 10-17, 22 and 24 under 35 USC § 112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner alleges that the original disclosure fails to recite the limitation of "CD4⁻ CD8⁻ CD25⁺ CD44^{+/+} double negative (DN) cells". We respectfully disagree as there is support for this phenotype on page 22, line 2 as well as in claim 20 as originally filed. However, in order to clarify the phenotype, claim 22 has been amended in order to specify the phenotypes (i) CD4⁻ CD8⁻ CD25⁺ CD44⁺ double negative T cells; and (ii) CD4⁻ CD8⁻ CD25⁺ CD44⁻ double negative T cells in order to avoid any ambiguity from use of the term CD44^{+/+}. Support for the fact that the cells can either be CD44⁺ or CD44⁻ can be found in the application as filed for example in Figure 5 and 9a.

In view of the foregoing, we respectfully request that the objections to the claims under 35 USC § 112, first paragraph be withdrawn.

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35 USC § 112, second paragraph

The Examiner has objected to claims 1, 2, 4, 8, 10-17, 22 and 24 under 35 USC § 112, second paragraph as being indefinite.

With regard to claim 1, the terms "(DP)" or "(DN)" have been removed from claim 1 and are not present in the pending claims.

Claim 8 has been deleted by the present amendment which renders the objection moot.

In view of the foregoing, we respectfully request that the objections to the claims under 35 USC § 112, second paragraph be withdrawn.

35 USC § 103

The Examiner has rejected claims 1, 2, 4, 8, 12-15, 17 and 22 under 35 USC § 103(a) as being unpatentable over Jaleco et al. (J. Exp. Med. 2001 194:991-1001), in view of Nakano et al. (Science 1994 265:5175) and Tatsumi et al. (Proc. Natl. Acad. Sci. 1990 87:2750-2754).

The Examiner notes at the bottom of page 5 of the office action that "Applicant would be successful in overcoming the above art rejection if they limited the claims to a method of producing mature T cells". We also note that such a claim amendment is also recommended in the interview summary wherein the Examiner requests that parts (a) and (b) of claim 1 are deleted. Therefore, in order to expedite allowance, claim 1 has been amended in order to delete parts (a) and (b). Pending claims 2, 4, 10-13 and 17 depend either directly or indirectly on claim 1 and therefore carry with them this limitation. Accordingly, these claims should also be free of the prior art.

As mentioned in the previous response, Jaleco et al. uses progenitor cells but is unable to produce any mature T cells. This lack of functionality was reiterated in the review of

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Lehar and Bevan where the authors stated that Jaleco et al. "were unable to generate any mature T cells" (Lehar and Bevan, p689). The system described by Nakano et al. does not permit the generation of any T cell lineage and therefore cannot teach a method for the generation of mature T cells. Only Tatsumi et al. teaches the generation of mature T cells. However, the precursor cells used in Tatsumi et al. were not stem cells or uncommitted progenitor cells. Claim 1 recites precursor cells that are stem cells or progenitor cells. Therefore none of the cited references were able to achieve the present invention wherein the generation of mature T cells is achieved using stem cells or progenitor cells.

With respect to claim 22, by the present amendment it has been rewritten into an independent claim that has incorporated the subject matter of previous claims 1 and 24. We note that previous claim 24 was not included in the obviousness rejection. Amended claim 22 relates to a method of expanding cells of the T cell lineage wherein the number of cells is increased by at least 10 to 15 fold. None of the cited references, either alone or in combination, teach a method of expanding T cells. In fact, Jaleco et al. observes that cellular expansion was considerably lower for cells cultured with Delta-1 stromal cells (Jaleco et al., pg.995). Tatsumi et al. used short-term cultures (1-3 days) and did not report increased T cell numbers whereas the system of Nakano et al. did not produce any T cells. The cited references do not teach a system for the 10 to 15 fold expansion of T cells that are produced using stem cells or progenitor cells as recited in amended claim 22.

In view of the foregoing, we respectfully request that the objections to the claims under 35 USC § 103(a) be withdrawn.

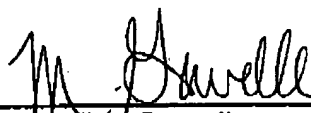
In view of the foregoing, we submit that the application is in order for allowance and an early indication to that effect would be greatly appreciated. Should the Examiner like to

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discuss the matter, he is kindly requested to contact Micheline Gravelle at 416-957-1682 at his convenience.

Respectfully submitted,

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